



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/682,098 | 07/19/2001 | Derek Bernhart | 3348.2 | 5280 |

37403 7590 04/08/2004

ATTENTION: MICHAEL VERGA
JAGTIANI + GUTTAG
10363-A DEMOCRACY LANE
FAIRFAX, VA 22030

EXAMINER

TO, BAOQUOC N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

2172

DATE MAILED: 04/08/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,098

Applicant(s)

BERNHART ET AL.

Examiner

Baoquoc N To

Art Unit

2172

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-44 are pending in this application.

Response to Arguments

2. Applicant's arguments with respect to claims 1 and 29 have been considered but are moot in view of the new ground(s) of rejection.

As to claims 20, 39 and 44, the applicant also argues "the terms "probe array" and "biological experiment", "attributes", and "identifiers" are misinterpreted by the examiner and these terms are well defined in the application specification."

The examiner respectfully disagrees with the above argument because the claims are interpreted in light of the specification, limitation from the specification are not read into the claim, *In re Van Guens* 988 F.2d 1181, 26 USPQ2d 1057 (Fed.Cir 1993). It is reminded that Applicant cannot rely on the specification to impart to the claims limitations not recited therein. Such reliance is ineffective to define over the prior art. *In re Lundberg*, 244 F2d 543, 113 USPQ 530 (CCPA 1957); *In re Winklans*, 188 USPQ 129 (CCPA 1975). Applicant are further reminded of the clear difference between reading the claim in light of the specification as allowed by 35 U.S.C. 112, 6th paragraph, and by *In re Donaldson* 29 USPQ2d, 1845, 16 F.3d 1189 (Fed. Cir, 1994), and reading limitations of the specification into the claims *In re Prater* 415 F2d 1393, 162 USPQ 541 (CCPA 1969). Further, the Applicants always have the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified, *In re Prater*, 162 USPQ 541, 550-51 (CCPA1969).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-19 and 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blevins (US. Patent No. 5,594,858) and in view of Balaban et al. (US. Patent No. 6,229,911 B1).

Regarding on claim 1, Blevins teaches a method for managing biological information related to a biological experiment comprising:

(b) receiving a specification of an attribute for at least one of the one or more identifiers (user define attribute functions) (col. 7, lines 29-35);

(c) generating a data template including at least one of the one or more identifiers (data prompts) (col. 10, lines 1-5), wherein the data template is configured to receive a value of each at least one identifier (value for attributes) (col. 17, lines 6-10) which represents the attribute specified for that identifier for the biological experiment (lab) (col. 17, lines 45-50); and

(d) receiving by the data template a value for the at least one identifier in accordance with the attribute specified for the identifier(input value) (col. 17, lines 7-10).

Blevins does not explicitly teach providing one or more identifier related to the use of the probe array used to acquire the biological information. However, Blevins teaches, "the selection portion 224 provides a list of data prompts related to processes associated with the particular project that may be selected by a user to created the unique control template or modify an existing control template" (col. 10, lines 1-5). This teaches data prompts are the identifiers related to the project. On the other hand, Balaban teaches, "a template type associated with each protocol template indicates that kind template. The template type identifies, for example, whether the template identifies parameters for experiments, for analysis, or for target preparation (col. 7, lines 56-61). This teaches creating the template for the experiment. Furthermore, Balaban also teaches "an analysis ID column identifies the analysis as listed in analysis table 438 that produced the relative gene expression result...A positive pairs ratio column lists the ratio of the numbers of positive probe pair between two targets (col. 12, lines 11-55). This teaches the uses of the probe array to obtain the gene sequences. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made to modify the probe array to obtain the gene expression into the Blevin in order to create template and use the probe array to obtain the gene expression to conduct the biological experiment.

Regarding on claim 2, Blevins teaches (e) storing the value for the at least one identifier in a data structure (col. 11, lines 20-25).

Regarding on claim 3, Blevins teaches the data structure is included in a database (template library) (col. 7, lines 18-20).

Regarding on claims 4 and 30, Blevins teaches the one or more identifiers comprise experiment identifiers (data prompts) (col. 10, lines 1-5) and the data templates comprise an experiment data template (list preferred or existing template) (col. 12, lines 1-10).

Regarding on claims 5 and 31, Blevins teaches the one or more identifiers comprise sample identifiers (data prompts) (col. 10, lines 1-5) and the data template comprises a sample data template (list preferred template) (col. 12, lines 1-10).

Regarding on claims 6 and 32, Blevins teaches the data structure comprises an experiment information file (col. 17, lines 28-33).

Regarding on claim 7, Blevins teaches displaying, prior to step (d), the data template to a first user (col. 9, line 60).

Regarding on claim 8, Blevins teaches the value is provided by the first user responsive to displaying the data template (col. 17, lines 5-10).

Regarding on claim 9, Blevins teaches the value is provided by the first user in accordance with a first type attribute (col. 17, lines 5-10).

Regarding on claim 10, Blevins teaches the first type attribute is a data attribute, time attribute, integer attribute, floating point, data attribute, character string attribute, required attribute, or controlled attribute (col. 17, lines 43-49).

Regarding on claim 11, Blevins teaches the value is provided by the first user in accordance with a required attribute (col. 17, lines 5-10).

Regarding on claim 12, Blevins teaches the required attribute specifies that the value is either required or not required to be received (col. 17, lines 29-31).

Regarding on claim 13, Blevins teaches the value is provided by the user in accordance with a controlled attribute (col. 17, lines 45-50).

Regarding on claim 14, Blevins teaches the controlled attribute specifies that the value is to be one or more of a plurality of user-specified values specified by a second user (col. 17, lines 45-50).

Regarding on claim 15, Blevins teaches the first and second users are different users (col. 10, lines 40-45).

Regarding on claims 16 and 36, Blevins teaches (f) storing instrument information for at least one instrument in the data structure, wherein the instrument is included in an experiment related to the probe array (col. 17, lines 25-30).

Regarding on claims 17 and 37, Blevins teaches (f) storing image in the data structure, wherein the image data is based, at least in part, on scanning of the probe array (col. 7, lines 25-35).

Regarding on claims 18 and 38, Blevins teaches (g) analyzing the image data to generate results data (col. 17, lines 25-30); and

(h) storing the results data in the data structure (col. 17, lines 35-40).

Regarding on claim 19, Blevins teaches (i) tracking the value, the image data, and the result data (col. 7, lines 18-19).

Regarding on claim 29, Blevins teaches a computer program product, comprising:

(a) a template generator (generator 124) (col. 7, lines 18-20) that generates a data template including one or more identifiers (attributes) (col. 7, lines 10-15) of a biological experiment with probe arrays;

(b) a value receiver (attributes) that receives values for the identifiers in accordance with their attributes (col. 7, lines 41-45); and

(c) a data storage manager that stores values in a data structure (col. 7, lines 41-45);

wherein the values (input values) are based on one or more experiments on one or more probe arrays (col. 7, lines 65-67).

Blevins does not explicitly teach template is created for biological experiment with a probe arrays. However, Blevins teaches, "a particularly selected control template attribute such as temperatures, pressures, and the like, to be further discussed below" (col. 11, lines 13-15). This indicates that the attributes such as temperatures and pressure are the parameters for the lab experiment. On the other hand, Balaban teaches, "a template type associated with each protocol template indicates that kind template. The template type identifies, for example, whether the template identifies parameters for experiments, for analysis, or for target preparation (col. 7, lines 56-61). This teaches creating the template for the experiment. Furthermore, Balaban also teaches "an analysis ID column identifies the analysis as listed in analysis table 438 that produced the relative gene expression result...A positive pairs ratio column lists the ratio of the numbers of positive probe pair between two targets (col. 12, lines 11-55). This teaches the uses of the probe array to obtain the gene sequences. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made to modify the probe array to obtain the gene expression into the Blevin in order to

create template and use the probe array to obtain the gene expression to conduct the biological experiment.

Regarding on claim 34, Blevins teaches a template generator generates the data template in response to a first user specifying at least one attribute of the one or more identifiers (col. 12, lines 1-5).

Regarding on claim 35, Blevins teaches the data template is selected by a second user (col. 10, lines 40-55).

4. Claims 20-28 and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blevins (US. Patent No. 5,594,858).

Regarding on claim 20, Blevins teaches a method for managing biological experiment information generated through the performance of an experiment with probe array, the method comprising the steps of:

(a) receiving from a first user a selection of a first data template (selects the type of control template to be create) having a plurality of identifiers (data prompts) (col. 12, lines 1-5) each identifying an attribute of the biological experiment (col. 11, lines 10-24);

(b) displaying (display screen) the first data template to the first user in response to the selection (col. 12, lines 30-37);

(c) receiving from the first user values (input value) for one more of the identifier (data prompts) (col. 10, lines 1-5) of the first data template in accordance with the attributes identified by the one or more identifiers (col. 7, lines 10-15); and

(d) saving the values in a data structure (col. 17, lines 35-40).

Blevins does not explicitly teach this is a biological experiment. However, Blevins teaches, "a particularly selected control template attribute such as temperatures, pressures, and the like, to be further discussed below" (col. 11, lines 13-15). This indicates that the attributes such as temperatures and pressure are the parameters for the lab experiment. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made modify the attributes in Blevins in order to conduct the biological experiment as claimed.

Regarding on claim 21, Blevins teaches the receiving step comprise the steps of:

(1) displaying a list of names of plurality of data templates (col. 7, lines 60-63);
and

(2) receiving from the first user, a selection of one of the displayed list of name a name of the first data template (col. 11, lines 60-63).

Regarding on claim 22, Blevins teaches the plurality of data templates include one or more default data templates (list preferred templates) (col. 12, lines 28-33).

Regarding on claim 23, Blevins teaches the list of names is displayed to the first user in a tree structure of a graphical user interface (col. 12, lines 1-4).

Regarding on claim 24, Blevins teaches the data structure includes an experiment information file (col. 12, lines 30-50).

Regarding on claim 25, Blevins teaches the experiment information file is included in a database (col. 12, lines 30-50).

Regarding on claim 26, Blevins teaches (e) generating the first data template based, at least in part, on a second user specifying the plurality of identifiers (col. 12, lines 30-50).

Regarding on claim 27, Blevins teaches generating the first template based, at least in part, on a second user specifying the attributes of the plurality of identifiers (col. 12, lines 60-62).

Regarding on claim 28, Blevins teaches the first and second users are different users (col. 10, lines 40-55).

Regarding on claim 39, Blevins teaches a computer implemented system for managing information of probe array experiments, comprising:

- A computer-readable storage medium (memory) (col. 5, lines 60-67);

- A database (library 11) (col. 6, line 1);

- A data template generator (template generator 124) coupled to the computer-readable storage medium (col. 7, lines 18-20); and

- An experiment manager (control template system) coupled to the computer readable storage medium and the database (col. 7, lines 18-20),

Wherein the data template generator generates at least one user-defined data template (selects the type of control template to be created) and stores (save) the user-defined data template on the computer-readable medium (col. 12, lines 1-5), each user-defined data template defining attributes of a set of experiment identifiers (col. 11, lines 10-15), a data template being selected from the at least one user-defined data template (a list of predefined or existing templates) (col. 12, lines 1-5) by a user using the

experiment manager, experiment identifiers being input (list of data prompts) (col. 10, lines 1-4) using the experiment manager according to the selected data template, the inputted experiment identifiers being stored in the database as an experiment information file (save) (col. 17, lines 34-36).

Blevins does not explicitly teach the experiment manager. However, Blevins teaches, "the control template system 120 includes the control template library 123 that communicates with the template generator 124" (col. 7, lines 18-20). Since the claim does not define what is the experiment manager. The examiner equates experiment manager is control template system 124. Therefore, it would have been obvious to one ordinary skill in the art at the time of the invention was made to modify the control template system to be experiment manager to allow the user to select the attributes and the system to generate the templates.

Regarding on claim 40, Blevins teaches instrument information is included in the experiment information file (col. 17, lines 25-35).

Regarding on claim 41, Blevins teaches a data processor couple to the database, for acquiring experiment data and storing the experiment data as an experiment data file in the database, a data analyzer, connected to the database, for analyzing result files in the database; and

A file manager (the control template library) for tracking the experiment file, the experiment data file, and analyzing results files (col. 7, lines 18-19).

Regarding on claim 42, Blevins teaches the experiment data file is an image file (col. 17, lines 25-35).

Regarding on claim 43, Blevins teach the file manager tracks the experiment information file, the experiment data file, and the analyzed results files according to the files names (col. 12, lines 18-37).

Regarding on claim 44 is rejected same as claim 39, in addition Blevins also teaches a computer-readable storage medium having at least one default data table stored thereon (predefined or existing templates) (col. 12, lines 1-5).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baoquoc N. To whose telephone number is (703) 305-1949 or via e-mail BaoquocN.To@uspto.gov. The examiner can normally be reached on Monday-Friday: 8:00 AM – 4:30 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Breene can be reached at (703) 305-9790.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231.


The fax numbers for the organization where this application or proceeding is assigned are as follow:

(703) 872-9306 [Official Communication]

Hand-delivered responses should be brought to:

Crystal Park II
2121 Crystal Drive
Arlington, VA 22202
Fourth Floor (Receptionist).

Baoquoc N. To
March 24, 2004


JEAN M. CORRIELLUS
PRIMARY EXAMINER